K061881

MAR 14 2007

510(k) Summary

OSTEOTRANS™-MX

Bioabsorbable Bone Fixation System

Submitter's name :	Takiron Co., Ltd.
Submitter's address:	3-13 Azuchi-machi 2-chome, Chuo-ku, Osaka 541-0052, Japan
Contact Person :	Kunihiro Hata Regulatory Affairs Specialist 405 Nagano, Yasutomi-cho, Himeji, Hyogo, 671-2421, Japan Phone: +81 790 66 2411 Fax: +81 790 66 3717
Date prepared:	June 28, 2006
Trade or proprietary name:	OSTEOTRANS™-MX Bioabsorbable Bone Fixation System
Common or usual name:	Bone Fixation Plate and screw
Classification name:	Plate, Fixation, Bone , Class II
Device product code:	As shown in 21 CFR 872.4760 bone plates are classified as Class II. Bone plates have been assigned Product Code JEY

Establishment Registration Number:
Takiron Co., Ltd. has not yet obtained an Establishment Registration Number.

Legally Marketed Predicate Devices:
Inion CPS™ 1.5/2.0/2.5 Bioabsorbable Fixation System (K010352)
BioSorbFX™ O/M 2.0/2.4 Bioabsorbable Fixation System (K011569)
Synthes Poly (L-Lactide-co-Glycolide) Resorbable Fixation System (K030069)
MacroPoreMX Mandibular Fixation System (K000694)
LactoSorb Panels and Fasteners (K980927)

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Intended Use:

The OSTEOTRANS™-MX Bioabsorbable Bone Fixation System is indicated for use in trauma and reconstructive procedures in the craniofacial skeleton, which includes the facial cranium, mid-face, maxilla and mandible.

Device Description:

The OSTEOTRANS™-MX Bioabsorbable Bone Fixation System devices are the sterile, single-use bone plates, meshes and screws manufactured from composites of hydroxyapatite and poly-L-lactide (HA/PLLA). Plates, meshes and screws are provided with various shapes and sizes typical of other marketed fixation devices.

Used properly, in the presence of adequate immobilization, the OSTEOTRANS™-MX Bioabsorbable Bone Fixation System devices maintain accurate alignment of bone fractures and osteotomies.

Summary of Technology:

The OSTEOTRANS™-MX Bioabsorbable Fixation System has the same technological characteristics (i.e., design and material) when compared to the predicate devices. Performance data demonstrate that the OSTEOTRANS™-MX Bioabsorbable Bone Fixation System has the requisite strength and favorable degradation profile to provide sufficient and sustained bone fixation for intended uses.

Substantial equivalence

The OSTEOTRANS™-MX Bioabsorbable Bone Fixation System is indicated for the same uses and anatomical regions as the predicate devices.
The OSTEOTRANS™-MX Bioabsorbable Bone Fixation System has very similar physical design features and functional characteristics as the predicate devices.
Therefore the OSTEOTRANS™-MX Bioabsorbable Bone Fixation System is substantially equivalent in design, materials and intended use and principles of operation to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 14 2007

Mr. Kunihiro Hata
Regulatory Affairs Specialist
Takiron Company, Limited
405 Nagano, Yasutomi-Cho
Himeji, Hyogo
JAPAN 671-2421

Re: K061881
Trade/Device Name: OSTEOTRANS™-MX Bioabsorbable Bone Fixation System
Regulation Number: 872.4760
Regulation Name: Bone Plate
Regulatory Class: II
Product Code: JEY
Dated: March 9, 2007
Received: March 9, 2007

Dear Mr. Hata:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K061881

INDICATIONS FOR USE

Applicant: Takiron Co., Ltd.

510(k) Number (if known): K061881

Device Name: OSTEOTRANS™-MX Bioabsorbable Bone Fixation System

Indications For Use:

The OSTEOTRANS™-MX Bioabsorbable Bone Fixation System is indicated for use in trauma and reconstructive procedures in the craniofacial skeleton, which includes the facial cranium, mid-face, maxilla and mandible.

(Please do not write below this line—continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use_____

(Per 21 CFR 801.109)

Susan Runyon

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